



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,088	02/02/2004	Chin-Chih Chiang	OEP2003-01	9267
26709	7590	11/17/2006		EXAMINER
SHIHONG NICOLAOU 4931 ARROYO LINDO AVE. SAN DIEGO, CA 92117				AHMED, HASAN SYED
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,088	CHIANG, CHIN-CHIH	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6, 9 and 10 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6, 9 and 10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
 HUMERA N SHEIKH
 PRIMARY EXAMINER

TC-1600

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's: (a) amendments to the claims, (b) remarks, and (c) foreign priority document; all filed on 28 August 2006.
2. The amendment filed on 28 August 2006 has been entered.
3. The objection to the specification is withdrawn in light of the amendment.
4. The 35 U.S.C. 102(e) rejection-of-record is withdrawn in light of the amendment.
5. Currently pending claims 1-4, 6, 9, and 10 remain rejected under 35 U.S.C. 103(a).

* * * * *

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (b) as follows: Applicant failed to provide an English translation of foreign application TAIWAN 092125778. As such, the priority date of the instant application is interpreted as 2 February 2004, the U.S. filing date.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert, et. al. (U.S. 2003/0147926) in view of Ikeda, et. al. (U.S. 6,207,184).

Ebert, et. al. teach a topical gel formulation of oxybutynin as well as a method for treating bladder disorders using said topical gel (see above).

The disclosed formulation is comprised of 2.2 wt. % oxybutynin chloride salt; 58.8 wt. % of a short chain alcohol; and 2.0 wt % of a gelling agent (see example 10).

Although the Ebert, et. al. reference does not provide an example of a formulation with all excipients claimed by applicant, it teaches every excipient claimed, with the exception of diisopropanolamine:

- the short chain alcohols of instant claims 1 and 2, i.e., ethanol and isopropanol (see paragraph 0122);
- the gelling agents of instant claims 1, 3 and 4, i.e., CARBOPOL, CARBOMER and PEMULEN (see paragraph 0116);
- the permeation enhancers of instant claims 1 and 6 , i.e., *inter alia*, isopropyl myristate (see paragraph 0134);
- the moisturizer of instant claims 1 and 9, i.e., propylene glycol (see paragraph 0127); and
- the method for treating bladder disorders of instant claim 10 (see paragraph 0017).

Ebert, et. al. explain that combining the disclosed agents into a topical gel formulation is beneficial because it mitigates the adverse drug effects associated with oxybutynin therapy (paragraphs 0006 and 0007).

The Ebert, et. al. reference differs from the instant application in that it does not disclose the diisopropanolamine of instant claim 1.

Ikeda, et. al. teach a hydrophilic adhesive mass which may be used for transdermal delivery of pharmaceutical agents, such as oxybutynin chloride salt (see col. 1, lines 32-53; col. 4, lines 20-25; col. 4, line 51). The disclosed adhesive mass may comprise the diisopropanolamine of instant claim 1 (see col. 5, line 23).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to make a topical gel formulation of oxybutynin (comprising diisopropanolamine, a short chain alcohol, a gelling agent a permeation enhancer and a moisturizer) to treat bladder disorders, as taught by Ebert, et. al, in view of Ikeda, et. al. Motivation would come from mitigation of adverse drug effects associated with oxybutynin therapy, as taught by Ebert, et. al., as discussed above. Those of ordinary skill in the art would expect similar properties from the instant formulation, given the teachings of Ebert, et. al. and Ikeda, et. al.

* * * * *

Response to Arguments

Applicant's arguments filed on 28 August 2006 have been fully considered but they are not persuasive.

Applicant argues that the Ebert, et. al. reference does not teach or fairly suggest all the elements of the claims. See Remarks, page 5, third paragraph.

Examiner respectfully submits that the only instant limitation that the Ebert, et. al. reference does not teach is the one added by amendment, i.e. diisopropanolamine. However, Ikeda, et. al. render obvious the use of diisopropanolamine in a transdermal formulation comprising oxybutynin (see above). Thus, Ebert, et. al. in combination with Ikeda, et. al. render all instant claim obvious, as discussed above.

* * * * *

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

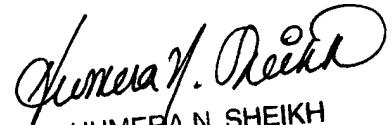
★ ★ ★ ★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


HUMERAN SHEIKH
PRIMARY EXAMINER

TC-1600